REMARKS

Claims 36-71 are pending and stand rejected. Applicants have canceled claims 37, 41, 50 and 65-68 without prejudice or disclaimer to the subject matter claimed therein. Claims 36, 38-40, 42, 43, 49, 61 and 63 have been amended. New claims 72-74 have been added. Reconsideration of the rejection is respectfully requested.

Applicants respectfully submit that the claim amendments and new claims are fully supported by the specification. In particular, support for the claimed feature of the implant being "arranged for placement in the body of a living being" can be found in the paragraph at the top of page 12, as well as in the title of the specification. Support for "the flowable soluble collagen gel being mixed with the non-soluble collagen fibers" finds support in the paragraph on page 58 discussing Figure 22. Support for the new claims 72-74 wherein the insoluble collagen fibers exclude the fibrillar (fibril) form of collagen at the highest level of structural organization is found in the inventor Declarations of 10/15/04 and 6/30/05.

Applicants believe that a brief review may be desirable to an enhanced understanding of the currently claimed embodiments of the present invention. It is directed to an implant suitable to be delivered to a tissue treatment site in the body of a living being. In particular, it is engineered to treat a bone defect, and even more specifically, it features an osteoconductive matrix that provides a scaffold and which permits ingress/egress of biological substances, specifically to encourage the growth and development of new bone within the structure of the implant. The implant features insoluble fibers and preferably native collagen fibers (for strength, among other uses) and a flowable biocompatible polymer. When it is ready to be implanted, the overall implant thus has a consistency of a putty or paste, and remains at least somewhat complaint following implantation. The viscosity or consistency feature is significant because it permits the implant material to be delivered to the defect site by way of a syringe, for example, and permits the implant material to flow to fill the defect site to a desired extent.

Claim Rejections - 35 USC §102

Claims 36, 37, 39, 43-50, 59-61 and 68 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,948,540 to Nigam et al. (hereinafter referred to as "Nigam"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Nigam neither discloses nor suggests the claimed invention. Specifically, Nigam neither discloses nor suggests an implant that is arranged to be placed into the body of a living being. In contrast, Nigam is a topical treatment for a wound; it is a bandage, not an implant. Moreover, Nigam neither discloses nor suggests the claimed characteristic of having the consistency of a putty just prior to the placement procedure. In contrast, Nigam's material has a putty or slurry consistency only at an intermediate stage of processing, not when the product is ready to be applied to a wound or other skin lesion. At the time of application, Nigam's product is a mechanically stable, conformable collagen

wound dressing sheet material. This sounds more like a cloth, not a putty, Applicants respectfully submit.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 36, 37, 39-50, 59-61 and 69-71 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,183,498 to Devore et al. (hereinafter referred to as "Devore"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Devore neither discloses nor suggests the claimed invention. Specifically, Devore neither discloses nor suggests the claimed tissue conductive matrix, nor the claimed osteoconductive matrix. An osteoconductive matrix is a type of tissue conductive matrix that specifically provides a scaffold for bone tissue in-growth. In other words, it is a matrix that encourages the ingress and growth of bone-related cells into itself. In contrast, Devore teaches a sealant—a material that stops the leakage of fluid from a tissue by stopping or avoiding the ingress of cells into itself, in this case, blood cells. A tissue conductive matrix is important to the claimed invention because an objective of the claimed implant is to permit ingress of biological material such as osteocytes (i.e., bone growth cells) so that the ingressed cells can grow and multiply, thereby forming new (bone) tissue. In addition, Devore teaches a sealant containing a chemical initiator to initiate polymerization after placement of the polymerizable protein at the leak site. Claim 36, having a "consisting of" format, does not recite and cannot be read to include such a polymerizing agent. Therefore, it is not anticipated by Devore, Applicants respectfully submit.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 36-49, 51-68, 70 and 71 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,294,187 to Boyce et al. (hereinafter referred to as "Boyce"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Boyce neither discloses nor suggests the claimed invention. Specifically, Boyce neither discloses nor suggests the claimed implant having a putty consistency just prior to implantation. Boyce teaches a load-bearing osteoimplant. Boyce discloses a putty consistency, but like Nigam, this is at an intermediate stage of processing, unsuitable for implantation, and does not represent the condition of his (finished) product at the time that it is ready to be implanted. Rather, the Boyce osteoimplant that is delivered to the implant site in the patient is a hard, chalk-like material (col. 11, lines 65-66).

Furthermore, Boyce neither discloses nor suggests the invention of independent claim 36 directed to an implant consisting of two phases: native insoluble collagen fibers, and a flowable biocompatible polymer. Boyce discloses a load-bearing osteoimplant which comprises a shaped, compressed composition of bone particles (col. 2, lines 34-37). As claim 36 does not recite bone particles, it should be patentable over Boyce, Applicants respectfully submit.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

The examiner requested that Applicants provide (i) the chemical process/method used on the instant application for extracting native/natural collagen fibers from corium or bovine hide; and (ii) the chemical process/method used on the instant application for incorporating/adding minerals to the matrix. The examiner stated that said methods could not be found in the instant application.

In response, Applicants respectfully submit that the chemical process or method for extracting native or natural collagen from corium or bovine hide is known in the art. For example, bovine hide in the form of lime splits may be first cut into centimeter-sized pieces and washed in water for several hours with agitation. The water is drained, and the washing step is repeated. Then, the hide pieces are neutralized and pH adjusted with an organic acid such as acetic acid to a pH of about 5 to 5.5 at a concentration of about 0.5% to 1.0%. After soaking in the mild acidic solution for several hours, the neutralized pieces of hide have a pH of about 5.8, and are then ground in a rotary type disc mill and rinsed, and the resulting fibers are then de-watered by freezing and thawing. Lastly, the fibers are lyophilized, first by cooling to a final temperature of about -20C to -60C, and then subliming the frozen water under a reduced pressure of about 125 millitorr. However, Applicants did not have to perform this extraction process in the instant application because one skilled in the art could consult Example II of Nigam for this teaching, specifically at column 3, line 59 through column 4, line 22. However, the skilled person does not need to refine native/natural / collagen fibers himself since such is a commercially available product, for example, Catalog No. C0381-02, "Collagen Native Typ II" from Chemos GmbH, Regenstauf, Germany. Collagen Corporation is another such commercial source.

As for incorporating/adding minerals to the matrix, Applicants respectfully submit that such incorporations may be made simply by physically blending or mixing the mineral into the collagen component of the osteoconductive matrix. See, for example, the paragraph discussing Figure 23, and in particular the sentence bridging pages 58 and 59 of the specification.

Applicants note the other art cited by the Examiner but not relied upon in the rejection.

In view of the above amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 36, 38-40, 42-49, 51-64 and 69-74.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,

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